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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/627,553

07/24/2003

Anthony Ross

044RE1

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30328

7590

03/27/2008

JONATHAN SPANGLER

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EXAMINER

PHILOGENE, PEDRO

ART UNIT

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3733

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/627,553	Applicant(s) ROSS ET AL.	
	Examiner Pedro Philogene	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-11 is/are allowed.
- 6) ☒ Claim(s) 12-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/22/08</u> . | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12, 13, 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berggren (2,995,159) in view of Adams et al (2,923,296).

With respect to claims 12, 24, Berggren discloses an injection device for injecting thermoplastic material, the injection device comprising a heating element (136) and a needle (44) for dispensing of the thermoplastic material. The thermoplastic capable of being heated to a flowable state at a predetermined temperature above the body temperature and thereafter cooling to return to a non-flowable state; as set forth in column 5, lines 29-30, and an injection device having a chamber (54) for receiving the thermoplastic material, a heating element (136) for heating the thermoplastic material to the flowable state, and a needle (44) for injecting the flowable thermoplastic material.

A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

With respect to claims 13, 19-23, Berggren discloses all the limitations, as set forth in column 3, lines 10-20, column 5, lines 29-30, and as best seen in FIGS. 1-10.

It is noted that Berggren does not teach of a needle having a diameter in the range from about six millimeters to about ten millimeters; as claimed by applicant. However, Adams et al evidence the use of a needle (13) having a diameter ranging from 6 millimeters to about ten millimeters, so that the solution flow can easily be controlled.

Therefore, given the teaching of Adam et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the needle of Berggren, as taught by Adams with a diameter from six millimeters to about ten millimeters so that the solution flow can be easily controlled.

Claims 12-16, 19-24 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Herskovitz et al. (4,357,136) in view of Adams et al (2,923,296).

With respect to claims 12, 24, Herskovitz et al disclose an injection device for injecting thermoplastic material, the injection device comprising a heating element (28,66) and a needle (38) for dispensing of the thermoplastic material. The thermoplastic capable of being heated to a flowable state at a predetermined temperature above the body temperature and thereafter cooling to return to a non-flowable state; and an injection device having a chamber, as best seen in FIG.2, for receiving the thermoplastic material, a heating element (28,66) for heating the thermoplastic material to the flowable state, and a needle (38) for injecting the flowable thermoplastic material.

A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to

patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

With respect to claims 13-16,19-23, Herskovitz et al. disclose all the limitations, as set forth in column 3, lines 30-67, column 4, lines 1-67, column 5, lines 1-38, and as best seen in FIGS.1-4.

It is noted that Herskovitz et al do not teach of a needle having a diameter in the range from about six millimeters to about ten millimeters; as claimed by applicant. However, Adams et al evidence the use of a needle (13) having a diameter ranging from 6 millimeters to about ten millimeters, so that the solution flow can easily be controlled.

Therefore, given the teaching of Adam et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the needle of Herskovitz et al, as taught by Adams with a diameter from six millimeters to about ten millimeters so that the solution flow can be easily controlled.

Claims 12-16, 19-24 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Rockaway et al. (4,684,344) in view of Adams et al (2,923,296).

With respect to claims 12, 24, Brockway et al disclose an injection device for injecting thermoplastic material, the injection device comprising a heating element (30) and a needle (42) for dispensing of the thermoplastic material. The thermoplastic capable of being heated to a flowable state at a predetermined temperature above the body temperature and thereafter cooling to return to a non-flowable state; and an

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injection device having a chamber (32), as best seen in FIG.1, for receiving the thermoplastic material, a heating element (30) for heating the thermoplastic material to the flowable state, and a needle (24) for injecting the flowable thermoplastic material.

A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

With respect to claims 13-16,19-23, Rockway et al. disclose all the limitations, as set forth in column 2, lines 15-67, column 3, lines 1-37, column 4, lines 1-15, and as best seen in FIGS.1-4.

It is noted that Rockaway et al do not teach of a needle having a diameter in the range from about six millimeters to about ten millimeters; as claimed by applicant. However, Adams et al evidence the use of a needle (13) having a diameter ranging from 6 millimeters to about ten millimeters, so that the solution flow can easily be controlled.

Therefore, given the teaching of Adam et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the needle of Rockaway et al, as taught by Adams with a diameter from six millimeters to about ten millimeters so that the solution flow can be easily controlled.

Claims 17-18 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Rockway et al. (4,684,344) in view of Mastrorio et al. (5,849,014) in view of Adams.

It is noted that Rockway et al did not teach of an expandable sleeve about the needle to define an annulus, so that pressurized fluid communication with the annulus expands the sleeve outwardly and the needle having openings; as claimed by applicant. However, in a similar art, Mastorio et al evidences the use of an expandable sleeve and a needle having openings for pressurizing the expandable sleeve to hold bone cement into the cavity.

Therefore, given the teaching of Mastrorio et al, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Rockway et al, as taught by Mastrotio et al to hold bone cement into the cavity.

It is noted that the above combination of references does not teach of a needle having a diameter in the range from about six millimeters to about ten millimeters; as claimed by applicant. However, Adams et al evidence the use of a needle (13) having a diameter ranging from 6 millimeters to about ten millimeters, so that the solution flow can easily be controlled.

Therefore, given the teaching of Adam et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the needle of Rockaway et al, as taught by Adams with a diameter from six millimeters to about ten millimeters so that the solution flow can be easily controlled.

Claims 17-18 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Herskovitz et al. (4,357,136) in view of Mastrorio et al. (5,849,014) in view of Adams .

It is noted that Herskovitz et al did not teach of an expandable sleeve about the needle to define an annulus, so that pressurized fluid communication with the annulus expands the sleeve outwardly and the needle having openings; as claimed by applicant. However, in a similar art, Mastorio et al evidences the use of an expandable sleeve and a needle having openings for pressurizing the expandable sleeve to hold bone cement into the cavity.

Therefore, given the teaching of Mastrorio et al, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Herskovitz et al, as taught by Mastrotio et al to hold bone cement into the cavity.

It is noted that the above combination of references does not teach of a needle having a diameter in the range from about six millimeters to about ten millimeters; as claimed by applicant. However, Adams et al evidence the use of a needle (13) having a diameter ranging from 6 millimeters to about ten millimeters, so that the solution flow can easily be controlled.

Therefore, given the teaching of Adam et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the needle of Herkovitz et al, as taught by Adams with a diameter from six millimeters to about ten millimeters so that the solution flow can be easily controlled.

Response to Amendment

Applicant's arguments, see Remarks, filed 11/23/07, with respect to the rejection(s) of claim(s) 1-24 under 102/103 have been fully considered and are

persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Adams. Adams discloses a needle having a diameter within the range of about six millimeters to about ten millimeters. Furthermore, since applicant amended the claims, applicant must also update the OATH.

Allowable Subject Matter

Claims 1-12 are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (571) 272-

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4716. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272 - 4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Pedro Philogene/
Primary Examiner, Art Unit 3733
March 24, 2008